31. (New) The pharmaceutical composition or dietary supplement according to claim 3, wherein the Butyrospermum-triterpene fraction and the sterol fraction comprises up to 100% (w/w) of the extract or concentrate of Butyrospermum parkii.

32. (New) The method according to claim 1, wherein the extract or concentrate of Butyrospermum parkii is derived from the fruit, leaves, stem, bark or root.

33. (New) The method according to claim 32, wherein the extract or concentrate of Butyrospermum parkii is derived from the fruit.

34. (New) The method according to claim 17, wherein said composition is as defined in any one of claims 2 to 9 or 26 to 33.

R E M A R K S

Claims 1-9 and 17-18 are currently under consideration. Claims 1-4 and 17-18 have been amended to remove objectionable phrases. Support for the Butyrospermum-triterpene fraction in claim 1 may be found at page 10, lines 1-10 of the Specification. Subject matter removed from claims 1-4 has been incorporated into the new claims. Support for new claims 32 and 33 is found on page 14, lines 19 to 26 of the Specification.

1. Rejections under 35 USC §112, first paragraph

The Examiner has rejected claims 17 and 18 for use of the phrase "prevention of hypersensitivity". The Examiner argues that the Specification does not enable a person of ordinary skill in the art to practice the full scope of the invention. Applicant has amended the claims to remove this phrase thereby obviating the rejection. Reconsideration and removal of the rejection is requested.

2. Rejections under 35 USC §112, second paragraph

The Examiner has rejected claims 1-9, 17 and 18 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner has objected to the inclusion of a narrow limitation which falls within a broad range or limitation within the same claim. Applicant has amended the claims to address this issue and have added new dependent claims with the removed subject matter. Reconsideration and removal of this rejection is respectfully requested.

3. Rejections under 35 USC §102(b)

The Examiner has rejected claims 1-5, 8-9 and 17-18 under 35 USC §102(b) as being anticipated by Zabotto et al. (US 4,661,343). The Examiner argues that this reference discloses a cosmetic preparation containing karite oil from the tree *Butyrospermum Parkii* and that the karite extract contains lupeol, stigmasterol, amyrin and butyrospermol in the instant amounts. The Examiner also argues that the reference discloses that karite oil is known for its protecting and softening effect on the skin. Applicant respectfully disagrees.

The Zabotto reference discloses a cosmetic compositions which comprises karite oil as a basic fatty acid component. The compositions of Zabotto contain much lower levels of the group of triterpenes than the compositions of the instant invention. A comparison of the compositions in the Zabotto reference versus the instant compositions appears in the attached Declaration and are

reproduced below. The cosmetic compositions of Zabotto et al. comprise:

triterpenic oil (%w/w):	0.001 - 0.180
α-Amyrin (%w/w):	0.0006 - 0.0828
β-Amyrin (%w/w):	0.0001 - 0.0180
Butyrospermol (%w/w):	0.0003 - 0.0468
Lupeol (%w/w):	0.0002 - 0.0288

whereas the compositions according to the present claim 1 comprise:

triterpenic oil (%w/w):	5
α-Amyrin (%w/w):	0.1
β-Amyrin (%w/w):	0.1
Butyrospermol (%w/w):	0.1
Lupeol (%w/w):	0.1

To anticipate a claim, the prior art reference must disclose each and every element of the claim. As seen in the charts above, the compositions of the Zabotto reference are not comparable to the compositions of the present invention. Notably, the Zabotto compositions do not contain at least 5% w/w triterpenic oils as required by the present claims. As such, Applicant submits that

the Zabotto reference does not anticipate the instant composition claims.

The Examiner has also rejected claims 17-19 which are directed to a method of treating hypersensitivity or inflammation in a mammal by administering the compositions according to the present invention. The Examiner argues that the Zabotto reference discloses the use of karite oil to protect and soften the skin. Applicant would like to first point out that Zabotto reference does not disclose Applicant's claimed compositions. Accordingly, Zabotto cannot anticipate a method of using these compositions for treatment purposes.

Applicant would also like to direct the Examiner to Example 2 of the present application which relates to the investigation of the anti-inflammatory effect of compositions comprising 1%, 5%, 10%, 15% and 20% of the triterpene extract recited in claim 1 upon application to the mouse ear in the phorbol ester induced inflammation mouse test, a widely used model for evaluating anti-inflammatory effect. The anti-inflammatory effect was evaluated by the ability to inhibit ear swelling. It was found that compositions comprising 1% of the triterpenic oil (≈0.02% of each of the triterpenes, α-amyrin and/or β-amyrin, butyrospermol and lupeol) did not inhibit the phorbol ester induced inflammation in mouse ear, whereas concentrations above 5% of the triterpenic oil (≈0.1% of each of the triterpenes, α-amyrin and/or β-amyrin, butyrospermol and lupeol) showed dose-dependent inhibition of the ear swelling. Thus, compositions comprising about 0.02% of α-amyrin and/or β-amyrin, butyrospermol and lupeol do not show any anti-inflammatory effect. The compositions of Zabotto, which comprise triterpenes, α-amyrin and/or β-amyrin, butyrospermol and

lupeol in levels of about 0.02% or less, would, therefore, not have any anti-inflammatory activity. This is further evidence that the Zabotto reference does not anticipate method claims 17-19.

The foregoing remarks demonstrate that the instant compositions are distinguishable from the Zabotto et al. reference. The remarks also demonstrate that the Zabotto et al. compositions do not demonstrate any anti-inflammatory properties/effect. As such, Applicant submits that the cited prior art reference fails to anticipate the instant claims. Reconsideration and removal of the rejection is respectfully requested.

4. Rejections under 35 USC §103(a)

The Examiner has rejected a number of claims under 35 USC §103(a) as being unpatentable over the combination of Zabotto et al. and the Journal or Pharmacology, GB 932662, SU 1181171 or Laur et al. (US Patent No. 5,679,393). Applicant respectfully disagrees for the reasons set below. The novelty and non-obviousness of the claims is also supported by the Rule 1.132 Declaration of Dr. Tonny Jørgenson submitted herewith.

A. Claim Rejection of Claim 18

The Examiner has rejected claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Zabotto et al , in view of the Journal of Pharmacology. The Examiner argues that the Journal of Pharmacology references discloses the application of shea butter to the nostrils to relieve inflammation. The Examiner contends that it would have been obvious to one of ordinary skill in the

art, at the time of the invention was made, to apply the compositions of Zabotto to mucous membranes.

As stated above, the compositions of the present invention are distinguishable from the compositions of Zabboto. Any obviousness rejection relying upon the Zabotto reference must therefore also fall. However, if the Examiner still considers the Journal of Pharmacology reference sufficient to render the claims obvious, Applicant submits that a person skilled in the art would not reach the same conclusions drawn by the Examiner. Simply stated, the Journal of Pharmacology reference does not teach how to relieve symptoms of anti-inflammatory diseases exemplified by atopic dermatitis, allergic contact dermatitis, psoriasis and osteoarthritis.

Specifically, the cited art reference only teaches that shea butter has a better effect than Xylomethazoline in relieving congestion upon application of the shea butter onto the mucosa of the nostrils. The reference teaches that when shea butter is applied to a nasal mucosa, it is expected to provide a better pharmacological response than a drug with α-adrenomimetic and vaso-constricting activity. A person of ordinary skill in the art would not relate this activity to any anti-inflammatory activity of shea butter. In other words, the teaching in the Journal of Pharmacology would not lead a person of skill in the art to expect that shea butter provides any general anti-inflammatory activity or provides any specific anti-inflammatory activity directed to atopic dermatitis, allergic contact dermatitis, psoriasis and/or osteoarthritis. As such, Applicant submits that neither Zabotto or the Journal of Pharmacology, singly or combination, anticipates or renders the present claims obvious.

B. Claim Rejection of Claims 6 and 7

The Examiner has rejected claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Zabotto et al. in view of SU 1181171 and rejected claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Zabotto et al in view of GB 932662. The Applicant wishes to remark that present claims 6 and 7 comprise further features related to the compositions recited in present claim 1. As already discussed above, the compositions of claim 1 are patentable over Zabotto et al. Therefore, Applicant submits that the present invention is not obvious in the light of the combined teachings of Zabotto et al. and GB 932662 or in the light of the combined teachings of Zabotto et al. and SU 1181171.

C. Rejection of Claims 1-5 and 7-9

The Examiner has rejected claims 1-5, and 7-9 under 35 U.S.C. § 103(a)as being unpatentable over Laur et al, US 5,679,393. The Examiner notes that the Laur et al. reference does not teach the instant amount of lupeol, amyrin, sterols, butyrospermol or the unsaponifiable material in an oral dosage form. However, the Examiner argues that the concentration of the unsaponifiable material in the composition would have been obvious to one of ordinary skill in the art since the concentration depends on the nature and process of extraction. Applicant respectfully disagrees.

The Laur et al. reference discloses compositions comprising a mixture of fractions rich in unsaponifiable materials obtained from shea butter (*see, for example, claim 14*) as having valuable properties for the fields of cosmetology, pharmacy, or medicine. According to Laur et al., such mixtures include mixtures of "cold-insoluble fractions" and "hot-insoluble" fractions consisting of

sterols, free-fatty acids, aliphatic and triterpene fatty alcohols, triglycerides and very apolar constituents such as karitenes and gum (*see* Example 5 at column 11, lines 46 to 51). Thus, Laur et al discloses a number of constituents to be present in compositions that possess valuable properties for the fields of cosmetology, pharmacy, or medicine. Laur does not disclose or suggest the compositions of the present invention. A person of ordinary skill in the art would not be motivated to prepare compositions containing the proper mixture of selected triterpenes and the dosage thereof for achieving anti-inflammatory effect as described in the instant application. Applicant specifically notes that Laur et al. does not teach the skilled person to provide compositions comprising at least 0.1% of each of the triterpenes, α-amyrin, β-amyrin, butyrospermol and lupeol for achieving the anti-inflammatory effect of the present invention. As such, Applicant submits that Laur does not render the present invention obvious as there is no teaching, suggestion or motivation in Laur to modify the compositions of Laur to arrive at the present invention. Reconsideration and removal of the rejection is respectfully requested.

D. Rejection of Claims 17 and 18

The Examiner has rejected claims 17 and 18 under 35 U.S.C. § 103(a) as being unpatentable over Laur et al. in view of WO 99/22706. The content of Laur et al. has been discussed above. The Examiner cites WO 99/22706 for disclosing Butyrospermum parkii as a dermatological, anti-inflammatory and vulnerary compound. The Examiner argues that it would have been obvious to a person of ordinary skill in the art to combine the teachings of the two references to arrive at the instant invention. Applicant respectfully disagrees.

The Examiner argues that it would have been obvious to use Laur et al's compositions containing shea butter fractions to prevent or treat inflammation since WO 99/22706 teaches that Buturyspermum parkii has anti-inflammatory properties. Applicant does not agree with the Examiner's opinion regarding the teaching of the WO 99/22706 reference. WO 99/22706 relates to compositions comprising extracts from the flower of Butyrospermum parkii. Such compositions are applicable for skin dryness, dermatitis and dermatosis, eczema, sunburns, and when refreshing, deodorising, astringent, toning, healing, anticrack, anti-wrinkle activities are required for oral hygiene. This group of applications is not comparable to the applications of the present invention that include treatment of inflammatory conditions that otherwise might have been treated with steroids or anti-inflammatory drugs (See Declaration, Appendix A), e.g. atopic dermatitis, allergic contact dermatitis, psoriasis and osteoarthritis. Therefore, given that the compositions of the present invention are distinguishable from those of Laur et al, Applicant submits that present claims 17 and 18 are patentable over the combined teachings of Laur et al and WO 9922706. Reconsideration and removal of the rejection is requested.

The compositions of the prior art are novel and useful in the treatment of inflammation, hypersensitivity and pain. The Declaration of Dr. Jørgensen and the above comments clearly establish the novelty and non-obviousness of the claims. Favorable action and the allowance of the claims are requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a three (3) month extension of time for filing a response in connection with the present application and the required fee of $ 460.00 is attached hereto.

The Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachments: Marked-Up Version of the Claims to Show Changes Made
Rule 1.132 Declaration of Tonny Jørgensen

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to Commissioner of Patents and Trademarks, Washington D.C. 20231 on: 8-12-02
(Date of deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

_____
(Signature)

August 12, 2002
(Date of Signature)

Marked Up Version of Amendments

1. (Amended) A pharmaceutical composition or a dietary supplement comprising [i)] an extract or concentrate of Butyrospermum parkii comprising [containing] at least 5% (w/w) of a Butyrospermum-triterpene fraction such that said composition comprises at least 5 % w/w of said Butyrospermum-triterpene fraction,

said Butyrospermum-triterpene fraction comprising:
- at least 2% (w/w) lupeol;
- at least 2% (w/w) α-amyrin and/or β-amyrin; and
- at least 2% (w/w) butyrospermol; [and]

[-optionally at least 1% germanicol, dammaradienol, 24-methylene-dammarenol and/or parkeol,]

wherein said triterpenes may be in the form of free alcohols or esters thereof [, especially cinnamic acid, acetic acid or fatty acid esters; and]

[ii) optionally a pharmaceutically acceptable carrier].

2. (Amended) The [A] pharmaceutical composition or a dietary supplement according to claim 1, wherein said Butyrospermum-triterpene fraction comprises [comprising]:
[i) an extract or concentrate of Butyrospermum parkii containing at least 5% (w/w) of a Butyrospermum-triterpene fraction comprising:]
- 10-40% (w/w) lupeol;
- 10-40% (w/w) α-amyrin and/or β-amyrin;
- 10-40% (w/w) butyrospermol. [;and]

[-optionally 2-30% germanicol, dammaradienol, 24-methylene-dammarenol and/or parkeol, wherein said triterpenes may be in the form of free alcohols or esters thereof, especially cinnamic acid, acetic acid or fatty acid esters; and
ii) optionally a pharmaceutically acceptable carrier.]

3. (Amended) The [A] pharmaceutical composition or dietary supplement according to claim 1 or 2, wherein [where] the extract or concentrate of Butyrospermum parkii further comprises a sterol fraction comprising at least one sterol selected from the group consisting of stigmasterol, avanasterol, 24-methyl-cholest-7-enol, karitesterol A, karitesterol B and α-spinasterol, wherein said sterols may be in the form of free alcohols or esters thereof [, especially cinnamic acid, acetic acid or fatty acid esters].

4. (Amended Twice) The [A] pharmaceutical composition or dietary supplement according to claim 1, wherein the Butyrospermum-triterpene fraction [optionally together with the sterol fraction] comprises up to 100% (w/w) of the extract or concentrate of Butyrospermum parkii.

5. (Amended) The [A] pharmaceutical composition or dietary supplement according to claim 3 [any of claims 3 or 4], wherein the ratio between the Butyrospermum-triterpene fraction and the sterol fraction is in the range of 1:100 to 500:1 (w/w).

6. (Amended Twice) The [A] pharmaceutical composition or dietary supplement according to claim 1, [which] further comprising [comprises] an extract of Calendula officinalis.

7. (Amended Twice) The [A] pharmaceutical composition according to claim 1 formulated for systemic administration.

8. (Amended Twice) The [A] pharmaceutical composition according to claim 1 formulated for topical administration [, wherein the pharmaceutical composition contains at least 5% (w/w) of the Butyrospermum-triterpene fraction].

9. (Amended) A pharmaceutical composition according to claim 8, wherein the pharmaceutical composition is formulated as a fluid, ointment, gel, liniment, emulsion [(e.g. cream or lotion)] or spray (e.g. aerosol).

17. (Amended Twice) A method for treating [treatment or prevention of] hypersensitivity or inflammation in a mammal, characterised by administering a composition [according to claim 1 to said mammal.] comprising

an extract or concentrate of Butyrospermum parkii comprising at least 5% (w/w) of a Butyrospermum-triterpene fraction such that said composition comprises at least 5 % w/w of said Butyrospermum-triterpene fraction,

said Butyrospermum-triterpene fraction comprises:
- at least 2% (w/w) lupeol;
- at least 2% (w/w) α-amyrin and/or β-amyrin; and
- at least 2% (w/w) butyrospermol;

wherein said triterpenes may be in the form of free alcohols or esters thereof.

18. (Amended Twice) The [A] method [for the treatment or prevention of inflammation or] according to claim 17, wherein the treating of hypersensitivity or inflammation is for the treating of hypersensitivity of the skin or mucous membranes of a mammal [characterised by administering a composition according to claim 1 to said mammal].